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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/570,233	04/28/2006	Dieter Willbold	23518	1858

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EXAMINER	
YOUNG, HUGH PARKER	
ART UNIT	**PAPER NUMBER**
1654	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/570,233	WILLBOLD ET AL.	
	Examiner	Art Unit	
	Hugh P. Young	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-23* is/are pending in the application.

4a) Of the above claim(s) *12-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10,11,15-19,22 and 23* is/are rejected.

7)☒ Claim(s) *20-21* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 February 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *Feb.28, 2006.*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This is the final Office action on application No. 10,570,233. There are fourteen claims pending, claims 1-9 having been canceled by Applicant.

Amendments in response to the first Office action on the merits

1. The amendment filed on January 22, 2007 under 37 CFR 1.312 has been entered.

2. Newly submitted claims 12-14 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the original invention, as claimed and searched, was drawn to a peptide of SEQ ID NO: 1. No other peptide sequences were claimed, nor were they properly recited in the disclosure.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 11-14 are withdrawn from consideration as being directed to a non-elected invention. Claims 10 and 15-23 will be examined only insofar as it pertains to the previously elected invention of SEQ ID NO: 1; the peptides of SEQ ID NOS: 2-27 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Objections to the specification

3. The disclosure is objected to because of the following informalities: the specification recites peptides, including dipeptides and polypeptides, beginning at line

20, page 3, through line 16, page 6, which do not have appropriate SEQ ID numbers in order to identify them as required; nor are they listed in the sequence listing submitted. The Brief Description of the Drawing on page 17 does not adequately describe 1) what the column (lane) headings correspond to by use of the appropriate SEQ ID numbers and 2) what the electrophoretic bands of interest correspond to, as discussed in the disclosure.

Appropriate correction is required.

Objections to the drawings

4. The drawings are objected to because they are so inadequately labeled as to fail to convey the information alluded to in the Specification. In the instant case they lack 1) typed or draftsman-lettered labeling for the English-language translation of the original German-language heading; 2) the bands of separated or isolated electrophoretic components are not labeled, either with text actually describing what they are, or with alphanumeric legends that would allow them to be referred to in the body of the disclosure, and 3) the Brief Description provided on page 17 of the Specification does not state what the column (lane) headings correspond to, especially which lanes correspond to the claimed invention; nor does it refer to the identity of the bands themselves (see also item 2, supra). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as

"amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Objections to the claims

5. Claim 19 is objected to because of the following informalities: it claims "glucoromic acid" as an ingredient of the composition claimed. There is not such substance and the term appears to be either a mistranslation from the original non-English text or a typographical error. Appropriate correction is required.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 10, 11 and 15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims do not state that the peptide sequence claimed, SEQ ID NO: 1, is isolated, purified, synthesized or made by recombinant means, thus showing the action of the hand of man. This rejection was made to the original claims in the first Office action and Applicant has not amended the claims so as to address the basis of the rejection.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 15-18 and 22-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case Applicant has not provided sufficient evidence that their claimed invention, the peptide sequence of SEQ ID NO: 1, can be used to practice the pharmaceutical composition of claims 15-18. For the purposes of this examination the dependency of the instant amended (new) claim 15 upon the withdrawn claim 1 of the original submission is interpreted as being drawn to the peptide of SEQ ID NO: 1, as examined in the first Office action on the merits of the claims. Applicant's sole support for claiming a pharmaceutical composition

is the test results presented in the sole example on page 18 of the amended Specification. This experiment, as disclosed, is incomplete and confusing: 1) the test description does not inform one as to when the subject peptide were exposed to the target PrP proteins and 2) which protein/peptide bands in the submitted Figure 1 correspond to which materials, variously or possibly including the intact PrP proteins, any breakdown products, or the peptides applied that are the subject of the invention. Applicant thus provides no evidence that the peptide of the invention works or functions at the cellular level in vitro, let alone any support that the peptide can be administered to a mammal, including a human, with any expectation that it would have any effect at all. Peptides are known in the art to be the target or subject of a wide variety of protease and peptidase enzymes that will break them down, especially in the digestive tract. Furthermore peptides are known to elicit immune responses that will, at the very least, result in their precipitation and removal from the body and, in extremus, provoke such a severe allergic response that the recipient exposed to them will succumb and die. Applicant states in the last paragraph on page 10 of the Specification that the peptides "must be so applied that they reach the effective locations" without ever disclosing how this is to be done. The next sentence states that the "effective location is the brain, the spinal tissue and or the entire nervous system as well as other parts of the organism." This latter term encompasses the entire body, none of which, other than nerve cells, is subject to prion disease. The body organs known to be afflicted by spongiform encephalopathies, the brain and spinal cord, are known to be isolated from the rest of the body by the blood-brain barrier, which is effective at excluding many compounds

from access to the nervous tissues themselves. Applicant has made broad, blanket statements on page 11 that the active ingredient can be formulated in any of the pharmacologically acceptable formulations without, as above, any support to show that they would, in fact, work.

9. Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case Applicant has not provided sufficient evidence, as above, that their claimed invention, the peptide sequence of SEQ ID NO: 1, can be used to practice the pharmaceutical composition of claims 15-18. Similarly, modifications of and substitutions within or upon the elected peptide of SEQ ID NO: 1 are not adequately described, can be interpreted as to comprise a complete alteration and replacement of the declared sequence with another sequence entirely, and even encompasses replacing the peptide elected with a molecule that is not even a peptide. In summary, undescribed modifications and substitutions of an undescribed starting material are lacking an adequate written description.

Objections to the claims

10. Claims 20-21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hugh P. Young whose telephone number is (571)-272-4988. The examiner can normally be reached on 8:00 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hugh P. Young Ph.D. GAU1654

JON WEBER
SUPERVISORY PATENT EXAMINER